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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,821	12/07/2001	Hyun-Soo Kim	3267/FLK/CIP of 2867	9666

7590

03/27/2002

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

2

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,821

Applicant(s)

KIM ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/536,163.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1616

DETAILED ACTION***Priority***

This application indicates that it is a CIP of prior Application No. 09/536,163, filed 3/25/2000. However, the alleged continuation-in-part application was not "filed before the patenting or abandonment of or termination of proceedings on the first application or an application similarly entitled to the benefit of the filing date of the first application" 35 USC 120. Since no extensions of time were filed, Application No. 09/536,163 automatically became abandoned three months (11/9/2001) from the mailing date (8/9/2001) of a final rejection in said case. The present application was subsequently filed on 12/7/2001, as such, Applicant is not entitled to any priority benefit from Application No. 09/536,163.

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Korea on 3/25/1999. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application due to the above failure to perfect the CIP was filed more than twelve months thereafter.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1616

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 00/57857.

WO 00/57857 expressly discloses tablets and methods of preparing tablets containing active ingredients, Pearlitol SD 200 ®, crospovidone and other excipients falling within the scope of applicant's claims (Examples 1-13).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978) and *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (US Pat. 6,316,029).

Jain et al. teach tablets and methods of making the same which have a disintegration or dissolution time of less than about 60 seconds comprising active ingredient(s), spray-dried mannitol powder (Pearlitol ® SD200), cross-linked polyvinylpyrrolidone and other excipients and that fast dissolving and disintegrating dosage forms are advantageous as they are easier to administer to patients in the areas of pediatrics, geriatrics and patients having dysphagia (Column 5, lines 14-30, Column 6, lines 1-8, 50-68, Columns 7-9, Column 11, lines 15-50). It is taught that suitable disintegrants include lightly crosslinked PVP, cross-provide and croscarmellose sodium (Column 9, lines 28-31). It is taught that spray-dried mannitol is a direct compression grade powder (Column 14, lines 20-33). Examples are taught containing active

Art Unit: 1616

ingredient, spray-dried mannitol powder (Pearlitol ® SD200) and croscarmellose sodium (Column 19, lines 40-68, Column 20-21, Column 22, lines 1-10).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a tablet which disintegrates in less than 60 seconds and method of preparing the same comprising active ingredient(s), Pearlitol ® SD200, crospovidone and other excipients. However, the prior art amply suggests the same as it is known to prepare tablets which disintegrate in less than 60 seconds comprising an active ingredient, Pearlitol ® SD200, a disintegrant and other excipients and that cross linked PVP is suitable as a disintegrant. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to substitute cross-linked PVP for the croscarmellose sodium with the expectation that the tablet would also be as fast disintegrating.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

March 23, 2002


JOSE G. DEES
SUPERVISORY PATENT EXAMINER

1616

